

2. REMARKS / DISCUSSION OF ISSUES

Claims 1-5, 7, 10, 11, 15-19 and 36-40 are pending in the application.

Withdrawn Rejections

Applicants gratefully acknowledge the withdrawal of the rejections under 35 U.S.C. § 102.

Rejections under 35 U.S.C. § 101

Claims 1-5, 7, 10, 11, 15-19 and 36-40 are rejected under 35 U.S.C. § 101 as allegedly lacking utility. Applicants respectfully submit that all claims constitute statutory subject matter.

Claim 1 recites:

A method for the spatially resolved determination of physical, chemical and/or biological properties or state variables, particularly substance concentrations, temperature, pH and/or physical fields, and/or the change in such physical, chemical and/or biological properties or state variables in an examination area of an examination object by determining a change in spatial distribution and/or mobility of magnetic particles in the examination area or in parts thereof as a function of the effect of physical, chemical and/or biological influencing variables on at least a part-area and/or in the physical, chemical and/or biological conditions in at least a part-area of the examination area, the method comprising:

- a) introducing coated magnetic particles having a coating into at least part of the examination area,*
- b) generating a magnetic field with a spatial profile of the magnetic field strength such that there is produced in the examination area a first part-area having a low magnetic field strength and a second part-area having a higher magnetic field strength,*

- c) changing the relative spatial position of the first and second part-areas in the examination area or changing the magnetic field strength in the first part-area so that the magnetization of the particles is locally changed,*
- d) detecting signals that depend on magnetization in the examination area that is influenced by said changing, and*
- e) evaluating the signals so as to obtain information about change in the spatial distribution and/or mobility of the magnetic particles in the examination area, wherein the coating is degradable and inhibits mobility of the particles.*

Claims 39 and 40 include features similar to those of claim 1 discussed presently.

35 U.S.C. § 101 states:

“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.”

Applicants respectfully submit that the claims under examination are directed to statutory subject matter; specifically a process.

MPEP § 2107.01 states:

“Practical utility is a shorthand way of attributing “real-world” value to claimed subject matter. In other words, one skilled in the art can use a claimed discovery in a manner which provides some immediate benefit to the public.”

Applicants respectfully submit that the evaluation of signals to obtain information about a change in spatial distribution and/or mobility of magnetic particles allows for the indirect measurement, for example, of temperature and pH. Clearly, an immediate benefit to the public is provided by the claimed invention. For purposes of illustration, as noted in the filed application (e.g., see page 14 of the filed application), a method allows a very accurate measurement of the temperature in an examination with accuracies to about 0.1 °C. Therefore, and at least in view of the reasons presented, Applicants

respectfully submit that claims 1-5, 7, 10, 11, 15-19 and 36-40 provide utility, and as such are statutory subject matter.

The Office Action asserts that the claimed invention “encompasses a process of basic research drawn to studying unspecified properties (physical, chemical and/or biological or state variable) by means of unspecified evaluation process of signals derived from varying magnetic field strengths in the presence of magnetic particles. The instant claims fail to specify any particular property and, further, fail to specify the [sic] a particular series of steps for evaluating signals so as to obtain a meaningful evaluation of spatial distribution and/or particle mobility.”

While Examination Guidelines are cited, there is no basis in law presented in support of the asserted deficiencies of the claims under examination. The failure to present legal basis (as opposed to examination guidelines) for a rejection is wholly improper in the determination of patentability.

Moreover, the Office Action asserts: “As noted under utility guidelines (see Federal Register, December 21, 1999, Vol. 64, No. 244), basic research on a product to identify properties is an insubstantial utility (see page 6 of the Utility guideline training materials). Therefore, the instant claims lack a specific and substantial utility.” At the outset, Applicants again note that examination guidelines do not have the effect and impact of law, and cannot form a basis of rejection as proffered in the Office Action. This notwithstanding, as noted above, claims 1-5, 7, 10, 11, 15-19 and 36-40 provide practical utility, and as such are statutory subject matter.

Furthermore, Applicant again direct attention to MPEP § 2107.01, which addresses the error in examination that can occur when ‘labels’ are attempted. To wit, MPEP § 2107.01 states:

“Some confusion can result when one attempts to label certain types of inventions as not being capable of having a specific and substantial utility based on the setting in which the invention is to be used. One example is inventions to be used in a research or laboratory setting. Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have a clear, specific and unquestionable utility (e.g., they are useful in analyzing compounds). An assessment that focuses on whether an invention is useful only in a research setting thus does not address whether the invention is in fact “useful” in a patent sense. Instead, Office personnel must distinguish between

inventions that have a specifically identified substantial utility and inventions whose asserted utility requires further research to identify or reasonably confirm. Labels such as "research tool," "intermediate" or "for research purposes" are not helpful in determining if an applicant has identified a specific and substantial utility for the invention."

Applicants' method is a new and useful process for the determination of a number of possible variables. For example, the method of Applicants' claim 1 comprises *introducing coated magnetic particles; changing the relative spatial position of the first and second part-areas in the examination area or changing the magnetic field strength in the first part-area so that the magnetization of the particles is locally changed, detecting signals; and evaluating the signals so as to obtain information about change in the spatial distribution and/or mobility of the magnetic particles in the examination area.* Clearly, the obtaining of information as specifically recited in claims 1, 39 and 40 has specific and substantial utility.

The Office Action also asserts that the claims "fail to specify what useful information would necessarily result from practicing the instant claims." The basis of whether claimed subject matter is statutory subject matter by the proffered test is not presented in the Office Action. Applicants respectfully submit assuming *arguendo* but not conceding that the captioned portion of the Office Action is a valid test of statutory subject matter, claims 1, 39 and 40 meet this test. To this end, evaluation of the signals provides information obtained about changes in the spatial distribution and/or mobility of *magnetic particles in an examination area.* The information thus obtained from the evaluation of signals allows *determination of physical, chemical and/or biological properties or state variables.* As noted above, an immediate benefit to the public is provided by the claimed invention. The claims under examination, therefore, provide practical utility.

For at least the reasons set forth above, Applicants respectfully submit that the rejections of claims 1-5, 7, 10, 11, 15-19 and 36-40 under 35 U.S.C. § 101 are improper and should be withdrawn.

Rejections under 35 U.S.C. §112, ¶1

Claims 1-5, 7, 10, 11, 15-19 were rejected under 35 U.S.C. §112, ¶1. The Office Action states:

“Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.”

Accordingly, it appears that the present rejection is for alleged lack of an enabling disclosure.

Applicants again respectfully submit that for at least the reasons set forth above, the claimed invention satisfies all requirements of 35 U.S.C. § 101, and as such, to the extent germane to the enablement requirement under 35 U.S.C. §112, ¶1, is compliant therewith.

Furthermore, Applicants direct attention to the nearly 19 pages of disclosure that provides full and clear support for the claimed invention, and, therefore, presents sufficient detail to enable one of ordinary skill in the art to make and use the invention.

Finally, the Office Action has failed to present any evidence whatsoever in support of the assertion that an enabling disclosure has not been presented. Applicants respectfully submit that the rejection is improper at least because of this deficiency.

Conclusion

In view the foregoing, applicant(s) respectfully request(s) that the Examiner withdraw the objection(s) and/or rejection(s) of record, allow all the pending claims, and find the application in condition for allowance.

If any points remain in issue that may best be resolved through a personal or telephonic interview, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

Respectfully submitted on behalf of:
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